EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

VERONICA LONGWELL and JAMES CHILDS, Individually and on behalf of all others similarly situated, Plaintiffs, v. CAMBER PHARMACEUTICALS, INC. -and- HETERO USA INC. Defendants.	Civil Action No. 1:19-cv-07463 **Jury Trial Demanded** **First Amended Complaint-Class Action**

FIRST AMENDED CLASS ACTION COMPLAINT

Plaintiffs Veronica Longwell and James Childs ("Plaintiffs"), individually and on behalf of all others similarly situated, bring this action against Camber Pharmaceuticals, Inc. ("Camber"), and Hetero USA Inc. ("Hetero") or ("Defendants"). Plaintiffs' allegations are based upon personal knowledge, the investigation of counsel, and information and belief.

I. INTRODUCTION

1. Plaintiffs bring this action on behalf of themselves and hundreds of thousands of other Valsartan consumers who paid for Defendants' generic Valsartan that was adulterated through its contamination with an IARC- and EPA-listed probable human carcinogen known as N-nitrosodimethylamine ("NDMA").

2. At all times during the period alleged herein, Defendants represented and warranted to consumers that their generic Valsartan products were therapeutically equivalent to and otherwise the same as brand DIOVAN®, were otherwise fit for their ordinary uses, and were otherwise manufactured and distributed in accordance with applicable laws and regulations.

3. However, for years, Defendants willfully ignored warnings signs regarding the

operating standards at the Zhejiang Huahai Pharmaceuticals ("ZHP") manufacturing plant in China, and Hetero Laboratories facilities ("HLF") in India, and continued to allow ZHP and HLF to manufacture their Valsartan products for sale to consumers in the United States even after Defendants knew or should have known that their Valsartan products manufactured by ZHP and HLF contained or likely contained NDMA and/or other impurities.

4. These adulterated Valsartan drugs were introduced into the American market at least as far back as 2015 for Defendants to profit from their sale to American consumers, such as Plaintiffs and Class Members. However, evidence now suggests that the contamination dates back at least as far as 2012. Plaintiffs and Class Members paid for all or part of their Valsartan prescriptions that were illegally introduced into the market by Defendants and which were not fit for their ordinary use. Defendants have been unjustly enriched through the sale of these adulterated drugs since at least 2012. Defendants' conduct also constitutes actionable common law fraud, consumer fraud, and other violations of state law.

II. PARTIES

5. Plaintiff Veronica Longwell is a U.S. citizen who resides and is domiciled in Massachusetts. During the class period, she paid money for one or more of Defendant Camber's Valsartan products. Defendant Camber expressly and impliedly warranted to Plaintiff Longwell that their respective generic Valsartan products were the same as brand Diovan. Had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Longwell would not have paid for Defendants' Valsartan products.

6. Plaintiff James Childs is a U.S. citizen who resides and is domiciled in New Jersey. During the class period, he paid money for one or more of Defendant Camber's Valsartan products. Defendant Camber expressly and impliedly warranted to Plaintiff Childs that their respective generic Valsartan products were the same as brand Diovan. Had Defendants' deception about

impurities within their products been made known earlier, Plaintiff Childs would not have paid for Defendants' Valsartan products.

7. Defendant Camber Pharmaceuticals ("Camber") is a Delaware limited liability company with its principal place of business located at 1031 Centennial Ave, Piscataway Township, NJ 08854. On information and belief, none of Camber's members are domiciled in Massachusetts. At all times material to this case, Camber has been engaged in the manufacturing, sale, and distribution of adulterated generic Valsartan in the United States, including in the Comonwealth of Massachusetts.

8. Defendant Hetero USA Inc. ("Hetero USA") is a Delaware limited liability company with its principal place of business located at 2002 Eastpark Blvd., Cranbury, New Jersey 08512. On information and belief, none of Hetero USA's members are domiciled in Massachusetts. At all times material to this case, Hetero has been engaged in the manufacturing, sale, and distribution of adulterated generic Valsartan in the United States, including in the Commonwealth of Massachusetts.

9. Defendant Hetero Drugs, Limited ("Hetero") is an Indian company, organized under the laws of India, with its principal place of business located at 7-2-A2, Hetero Corporate, Industrial Estates, Sanath Nagar, Hyderabad – 500 018 A.P. India. On information and belief, Hetero exercised control over subsidiary and/or affiliate entities that sold generic Valsartan in the United States, including but not limited to Camber and Hetero USA. At all times material to this case, Hetero engaged in the manufacturing, sale, and distribution of adulterated generic Valsartan in the United States, including in the Commonwealth of Massachusetts, and purposefully availed itsef of doing business in the United States and Massachusetts.

III. JURISDICTION AND VENUE

10. This Court has original jurisdiction pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d), because (a) at least one member of the proposed class is a citizen of a state different from that of Defendants, (b) the amount in controversy exceeds $5,000,000, exclusive of interest and costs, (c) the proposed class consists of more than 100 class members, and (d) none of the exceptions under the subsection apply to this action. In addition, this Court has original jurisdiction pursuant to 28 U.S.C. § 1331.

11. This Court has personal jurisdiction over Defendants because each Defendant has sufficient minimum contacts in Massachusetts (and the United States generally) and otherwise intentionally avails itself of the markets within Massachusetts through its business activities, such that the exercise of jurisdiction by this Court is proper and necessary.

12. Venue is proper in this District because: Plaintiffs Longwell and/or Childs reside in this District, 28 U.S.C. § 1391(b)(1); because "a substantial part of the events or omissions giving rise to the claim occurred" in this District, 28 U.S.C. § 1391(b)(2); and because Defendants are subject to the personal jurisdiction of this Court, 28 U.S.C. § 1391(b)(3).

IV. FACTUAL ALLEGATIONS

A. Valsartan Background

13. Valsartan is a potent, orally active nonpeptide tetrazole derivative which causes a reduction in blood pressure, and is used in the treatment of hypertension, heart failure, and post-myocardial infarction.

14. Valsartan is the generic version of the registered listed drug ("RLD") DIOVAN® ("Diovan"), which was marked in tablet form by Novartis AG ("Novartis") beginning in July 2001 upon approval by the U.S. Food and Drug Administration ("FDA").

15. Diovan was an immensely popular drug. Globally, Diovan generated $5.6 billion

in sales in 2011 according to Novartis's Form 20-F for that year, of which $2.33 billion was from the United States.

16. Diovan's FDA-approved label specifies its active and inactive ingredients. NDMA is not an FDA-approved ingredient of Diovan. Nor is NDMA an FDA-approved ingredient of any generic Valsartan product.

17. Although Novartis's Diovan patents expired in September 2012, Novartis was spared generic competition until approximately June 2014 because Ranbaxy Pharmaceuticals (the generic exclusivity holder) was unable to achieve FDA approval for its generic Diovan, thus effectively preventing other generic competition under the Hatch-Waxman Act, until Ranbaxy achieved FDA approval and began to market its generic product.

B. The Generic Drug Approval Framework

18. The Drug Price Competition and Patent Term Restoration Act of 1984 – more commonly referred to as the Hatch-Waxman Act – is codified at 21 U.S.C. § 355(j).

19. Brand drug companies submitting a New Drug Application ("NDA") are required to demonstrate clinical safety and efficacy through well-designed clinical trials. 21 U.S.C. § 355 et seq.

20. By contrast, generic drug companies submit an Abbreviated New Drug Application ("ANDA"). Instead of demonstrating clinical safety and efficacy, generic drug companies need only demonstrate bioequivalence to the brand or reference listed drug ("RLD"). Bioequivalence is the "absence of significant difference" in the pharmacokinetic profiles of two pharmaceutical products. 21 C.F.R. § 320.1(e).

21. The bioequivalence basis for ANDA approval is premised on the generally accepted proposition that equivalence of pharmacokinetic profiles of two drug products is accepted as evidence of therapeutic equivalence. In other words, if (1) the RLD is proven to be safe and

effective for the approved indication through well-designed clinical studies accepted by the FDA, and (2) the generic company has shown that its ANDA product is bioequivalent to the RLD, then (3) the generic ANDA product must be safe and effective for the same approved indication as the RLD.

22. In other words, generic drug manufacturers have an ongoing federal duty of sameness in their products. Under 21 U.S.C. § 355(j), the generic manufacturer must show the following things as relevant to this case: the active ingredient(s) are the same as the RLD, § 355(j)(2)(A)(ii); and, that the generic drug is "bioequivalent" to the RLD and "can be expected to have the same therapeutic effect," id. at (A)(iv). A generic manufacturer (like a brand manufacturer) must also make "a full statement of the composition of such drug" to the FDA. Id. at (A)(vi); see also § 355(b)(1)(C).

23. And finally, a generic manufacturer must also submit information to show that the "labeling proposed for the new drug is the same as the labeling approved for the [RLD][.]" 21 U.S.C. § 355(j)(2)(A)(v).

24. Upon granting final approval for a generic drug, the FDA will typically state the generic drug is "therapeutically equivalent" to the branded drug. The FDA codes generic drugs as "A/B rated" to the RLD branded drug. Pharmacists, physicians, and patients can fully expect such generic drugs to be therapeutically interchangeable with the RLD, and generic manufacturers expressly warrant as much through the inclusion of the same labeling as the RLD delivered to consumers in each and every prescription of it generic products.

25. According to the FDA, there are fifteen Abbreviated New Drug Applications ("ANDAs") approved for generic Diovan, i.e., Valsartan.

C. <u>Background on Current Good Manufacturing Practices ("cGMPs")</u>

26. Under federal law, pharmaceutical drugs must be manufactured in accordance with

"current Good Manufacturing Practices" ("cGMPs") to assure they meet safety, quality, purity, identity, and strength standards. See 21 U.S.C. § 351(a)(2)(B).

27. The FDA's cGMP regulations are found in 21 C.F.R. Parts 210 and 211. These detailed regulations set forth minimum standards regarding: organization and personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug product containers and closures (Subpart E); production and process controls (Subpart F); packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory controls (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K). The FDA has worldwide jurisdiction to enforce these regulations if the facility is making drugs intended to be distributed in the United States.

28. Any drug not manufactured in accordance with cGMPs is deemed "adulterated" and may not be distributed or sold in the United States. See 21 U.S.C. §§ 331(a), 351(a)(2)(B). Drugs are deemed to be adulterated if the manufacturer fails to comply with cGMPs to assure the drugs' safety, quality, purity, identity, and strength and/or if they are contaminated. See 21 U.S.C. § 351(a)(2)(A), (B). Federal law prohibits a manufacturer from directly or indirectly causing adulterated drugs to be introduced or delivered for introduction into interstate commerce. See id. § 331(a). States have enacting laws adopting or mirroring these federal standards.

29. Per federal law, cGMPs include "the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products." 21 U.S.C. § 351(j). Accordingly, it is a cGMP violation for a manufacturer to contract out prescription drug manufacturing without sufficiently ensuring continuing quality of the subcontractors' operations.

30. Indeed FDA regulations require a "quality control unit" to independently test drug

product manufactured by another company on contract:

> (a) There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company.

21 C.F.R. § 211.22(a).

D. <u>The Camber / Hetero USA Manufacturing Facilities</u>

31. Camber and Hetero USA are fully owned affiliates or subsidiaries of Hetero. Camber and Hetero USA , in connection with Hetero, maintain six (6) API Manufacturing facilities in India, which have been approved by the FDA to produce active ingredients for drugs being sold and marketed in the United States.

32. Hetero Pharmaceuticals Laboratories ("HLF"), another affiliated entity of Hetero, Camber, and Hetero USA, operates the Indian drug manufacturing facilities utilized by Camber and Hetero USA. Hetero exercises control over HLF as well as Camber and Hetero USA. HLF has a history of deviations from FDA's cGMP standards.

33. In December of 2016, during an inspection of an oral solid dose drug product manufacturing facility, the FDA observed, through closed circuit TV surveillance, that HLF Quality Assurance technicians and "other individuals" were recorded destroying and altering records pertaining to commercial batch manufacturing immediately before the FDA's onsite regulatory inspection. According to a scathing letter, the FDA noted that the following occurred:

a. HLF employees brought in a document shredder into the "DOCUMENTS STORAGE AREA" four days prior to the FDA inspection;
b. The FDA observed extensive shredding of what appeared to be "controlled documents" as well as "extensive signing of documents" by Quality Assurance technicians. The FDA noted that the documents were of a color consistent with

batch packaging records and batch manufacturing record. HLF failed to maintain documentation of what had been shredded;

c. One day prior to the FDA inspection an HLF contract employee in the Quality Assurance division removed documents from the shredder and placed them in his pocket; and
d. At 1:13am the morning the FDA inspectors were set to arrive to the HLF for their regulatory inspections, individuals were seen shredding documents.

34. In addition to the destruction of these manufacturing records, the FDA further observed that production and control records were not prepared for each batch of drug product produced and did not include complete information relating to the production and control of each batch.

35. Additionally, data derived from HLF's programmable logic controller for compression machines was inconsistent with batch records and validation reports that were submitted to the FDA in support of applications to manufacture and market drugs in the United States.

36. HLF also failed to include findings of any investigations and follow-up that occurred as a result of investations into complaints about their drugs.

37. During the December 2016 inspection, equipment at the HLF was found to have not been cleaned and maintained at appropriate intervals to "prevent contamination that would alter the safety, identity, strength, quality and purity" of HLF's drug products.

38. During the December 2016 visit, FDA inspectors found that "accuracy, sensistivity and reproducibility of test methods" were not established and documented.

39. In an August 15, 2017, warning letter from the FDA, the FDA strongly recommended that Hetero (and/or its affiliates and subsidiaries) engage "a consultant, qualified as set forth in 21 CFR 211.34" to assist Hetero Labs in meeting cGMP requiriments, but that, ultimately, "executive management remains responsible for fully resolving all deficiencies and ensuring ongoing cGMP compliance."

40. In Feburary of 2018, FDA investigators discovered other manufacturing flaws at an API manufacturing facility of Hetero's.

41. For example, the FDA found that there was a "failure" by HLF to "thoroughly review any unexplained discrepancy and failure of a bath or any of its components to meet any of its specifications" whether or not the batch had been already distributed.

42. The FDA investigators further found during that February 2018 inspection, that HLF employees engaged in the processing, holding and testing of a drug product lacked the training and experience required to perform their assitned functions. Indeed, in a walk-through with FDA investigators, several quality control personnel could not explain their assigned functions and processes after "repeated opportunities" to do so.

43. Additionally, FDA investigators concluded that there was "no assurance" that equipment used in API production was being maintained and/or kept under proper conditions for manufacturing operations and "to prevent the contamination of the products handled and/or processed in the equipment."

E. <u>Defendants Were Aware of Potential NDMA Contamination As Early As 2012</u>

44. Upon information and belief, Defendants, through their affiliated HLF facilities in India, utilized a manufacturing process which created NDMA as a carcinogenic by-product of its API.

45. If Defendants had not routinely disregarded the FDA's cGMPs, or had fulfilled their quality assurance obligations, Defendants would have found the NDMA contamination almost immediately.

46. 21 C.F.R. § 211.110 contains the cGMPs regarding the "Sampling and testing of in-process materials and drug products[.]" Subsection (c) states the following:

> In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process, e.g., at commencement or completion of significant phases or after storage for long periods.

21 C.F.R. § 211.110(c).

47. And as reproduced above, Defendants' own quality control unit are and were responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by HLF.

48. If these sampling-related and quality-control-related cGMPs were properly observed by Defendants, the NDMA contamination in Defendants' Valsartan products would have been discovered.

49. There are indications that Defendants had actual knowledge of Valsartan's contamination with NDMA, and made efforts to conceal or destroy the evidence.

50. As alleged above, FDA investigators visited HLF's facilities and found that HLF was wantonly and willfully flouting cGMCPs and actively destroying documentation regarding their manufacturing processes.

51. These discoveries by the FDA's investigators suggest that HLF was specifically aware of impurities in the drugs being manufactured by HLF, including specifically contamination of Defendants' Valsartan with NDMA. The efforts to manipulate data constituted an explicit effort to conceal and destroy evidence and to willfully and recklessly introduce adulterated Valsartan into the U.S. market.

52. And yet, Defendants knowingly, recklessly, and/or negligently introduced adulterated Valsartan into the U.S. market that was contaminated with NDMA. Defendants failed to recall their generic Valsartan products because they feared permanently ceding market share to competitors. And, upon information and belief, Defendants issued the "voluntary" recall of their

Valsartan products only after the FDA had threatened an involuntary recall.

F. FDA Announces Voluntary Recall of Defendants' Adulterated Valsartan

53. On or about July 27, 2018, the FDA announced expanded recalls of additional Valsartan products manufactured by Defendants and non-parties, and re-packaged by third parties.[1] The recall is for products distributed as early as October 2015.

54. On or about August 9, 2018, the FDA announced voluntary recalls by Defendants and other manufacturers for their Valsartan products manufactured by Defendants.[2] The recall is for products distributed as early as October 2015.

55. As stated in the FDA's July 13, 2018 statement:

> The U.S. Food and Drug Administration is alerting health care professionals and patients of a voluntary recall of several drug products containing the active ingredient valsartan, used to treat high blood pressure and heart failure. This recall is due to an impurity, N-nitrosodimethylamine (NDMA), which was found in the recalled products. However, not all products containing valsartan are being recalled. NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. The presence of NDMA was unexpected and is thought to be related to changes in the way the active substance was manufactured.

G. Defendants' Warranties and Fraudulent and Deceptive Statements to Consumers Regarding Their Generic Valsartan Products

56. Each Defendant made and breached express and implied warranties and also made affirmative misrepresentations and omissions to consumers about their adulterated Valsartan products.

57. The FDA maintains a list of "Approved Drug Products with Therapeutic

[1] FDA News Release, FDA UPDATES ON VALSARTAN RECALLS, *at* https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm (last accessed Oct. 26, 2018).

[2] FDA News Release, FDA ANNOUNCES VOLUNTARY RECALL OF SEVERAL MEDICINES CONTAINING VALSARTAN FOLLOWING DETECTION OF IMPURITY, *at* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm (last accessed Oct. 26, 2018).

Equivalence Evaluations" commonly referred to as the Orange Book.3 The Orange Book is a public document; Defendants sought and received the inclusion of their products in the Orange Book upon approval of their Valsartan ANDAs. In securing FDA approval to market generic Valsartan in the United States as an Orange Book-listed therapeutic equivalent to Diovan, Defendants were required to demonstrate that their generic Valsartan products were bioequivalent to brand Diovan.

58. Therapeutic equivalence for purposes of generic substitution is a continuing obligation on the part of the manufacturer. For example, according to the FDA's Orange Book, therapeutic equivalence depends in part on the manufacturer's continued compliance with cGMPs.

59. By introducing their respective Valsartan products into the United States market under the name "Valsartan" as a therapeutic equivalent to Diovan and with the FDA-approved label that is the same as that of Diovan, Defendants represent and warrant to end users that their products are in fact the same as and are therapeutically interchangeable with Diovan.

60. Each Defendant's Valsartan product is accompanied by an FDA-approved label. By presenting consumers with an FDA-approved Valsartan label, Defendants, as generic manufacturers of Valsartan, made representations and express or implied warranties to consumers of the "sameness" of their products to Diovan, and that their products were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels and/or were not adulterated.

61. In addition, on information and belief, each Defendant affirmatively misrepresented and warranted to consumers through their websites, brochures, and other marketing

[3] FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (ORANGE BOOK) SHORT DESCRIPTION, *at* https://www.fda.gov/drugs/informationondrugs/approveddrugs/approveddrugproductswiththerapeuticequivalenceevaluationsorangebook/default.htm (last accessed Aug. 31, 2018).

or informational materials that their Valsartan product complied with cGMPs and did not contain (or were not likely to contain) any ingredients besides those identified on the products' FDA-approved labels.

62. The presence of NDMA in Defendants' Valsartan: (1) renders Defendants' Valsartan products non-bioequivalent (i.e., not the same) to Diovan and thus non-therapeutically interchangeable with Diovan, thus breaching Defendants' express warranties of sameness; (2) was the result gross deviations from cGMPs thus rendering Defendants' Valsartan products non-therapeutically equivalent to Diovan, thus breaching Defendants' express warranties of sameness; and (3) results in Defendants' Valsartan containing an ingredient that is not also contained in Diovan, also breaching Defendants' express warranty of sameness (and express warranty that the products contained the ingredients listed on each Defendant's FDA-approved label). Each Defendant willfully, recklessly, and/or negligently failed to ensure their Valsartan products' labels and other advertising or marketing statements accurately conveyed information about their products.

63. At all relevant times, Defendants have also impliedly warranted that their Valsartan products were merchantable and/or fit for their ordinary purposes.

64. Naturally, due to its status as a probable human carcinogen as listed by both the IARC and the U.S. EPA, NDMA is not an FDA-approved ingredient in Valsartan. The presence of NDMA in Defendants' Valsartan means that Defendants have violated implied warranties to Plaintiffs and Class Members. The presence of NDMA in Defendants' Valsartan results in Defendants' Valsartan products being non-merchantable and not fit for its ordinary purposes (i.e., as a therapeutically interchangeable generic version of Diovan), breaching Defendants' implied warranty of merchantability and/or fitness for ordinary purposes.

65. For these and other reasons, Defendants' Valsartan is therefore adulterated it was

illegal for Defendants' to have introduced such Valsartan in the United States. See 21 U.S.C. §§ 331(a), 351(a)(2)(B).

66. Adulterated Valsartan is essentially worthless. No consumer would purchase an adulterated Valsartan product or is even allowed to purchase adulterated Valsartan product because it was illegally introduced into the United States. This is especially so given that alternative, non-adulterated Valsartan products or competing medications with the same approved indications were available from other manufacturers.

H. New Revelations Continue to Unfold About Other Manufacturing Plants

67. The recall of Defendants' Valsartan products is only the tip of the iceberg. Just two weeks after the FDA's initial recall announcement, the FDA issued another announcement expanding the recall to other Valsartan products.. On August 20, 2018 the FDA announced that it was going to test all Valsartan products for NDMA.4 Additionally, on October 30, 2018, the FDA announced a voluntary recall of irbesartan products, which is a product in the same drug class as Valsartan.[5] Because of Defendants' and non-parties' ongoing fraud and deception, the full scope of Defendants' and non-parties' unlawful conduct is not yet known.

I. Fraudulent Concealment and Tolling

68. Plaintiffs and Class Members causes of action accrued on the date the FDA announced the recall of Defendants' generic Valsartan products.

69. Alternatively, any statute of limitation or prescriptive period is equitably tolled on account of fraudulent concealment. Defendants each affirmatively concealed from Plaintiffs and other Class Members their unlawful conduct. Each Defendant affirmatively strove to avoid

[4] FDA Statement, STATEMENT FROM FDA COMMISSIONER, *at* http://freepdfhosting.com/1c7e5ed26e.pdf (last accessed Oct. 26, 2018).

[5] FDA, FDA ALERTS PATIENTS AND HEALTH CARE PROFESSIONALS TO SCIEGEN'S IRBESARTAN RECAL DUE TO NDEA, *at* https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm (last accessed Nov. 6, 2018).

disclosing their knowledge of cGMP violations with respect to Valsartan, and of the fact that their Valsartan products were adulterated and contaminated with NMDA, and were not the same as brand Diovan.

70. For instance, no Defendant revealed to the public that their Valsartan product contained NDMA or was otherwise adulterated or non-therapeutically equivalent to Diovan until the FDA's recall announcement in July 2018. The inspection report which preceded the recall announcement was heavily redacted (including the names of the drugs affected by cGMP violations), and prior inspection reports or warnings were not fully available to the public, if at all.

71. To the contrary, each Defendant continued to represent and warrant that their generic Valsartan products were the same as and therapeutically interchangeable with Diovan.

72. Because of this, Plaintiffs and other Class Members did not discover, nor would they discover through reasonable and ordinarily diligence, each Defendant's deceptive, fraudulent, and unlawful conduct alleged herein. Defendants' false and misleading explanations, or obfuscations, lulled Plaintiffs and Class Members into believing that the prices paid for Valsartan were appropriate for what they believed to be non-adulterated drugs despite their exercise of reasonable and ordinary diligence.

73. As a result of each Defendant's affirmative and other acts of concealment, any applicable statute of limitations affecting the rights of Plaintiffs and other Class Members has been tolled. Plaintiffs and/or other Class Members exercised reasonable diligence by among other things promptly investigating and bringing the allegations contained herein. Despite these or other efforts, Plaintiffs were unable to discover, and could not have discovered, the unlawful conduct alleged herein at the time it occurred or at an earlier time so as to enable this complaint to be filed sooner.

J. Plaintiff Veronica Longwell's Individual Facts

74. Plaintiff Veronica Longwell is a Massachusetts citizen who resides and is domiciled in Haverhill, Massachusetts.

75. On or about March 29, 2018, April 13, 2018, and June 8, 2018, Plaintiff Longwell purchased generic Valsartan manufactured by the Defendants and bearing NDC Number 317-220-746-90. Plaintiff Longwell paid copays of $5.41, $15.55, and $10.87, respectively.

76. The generic Valsartan purchased by Plaintiff Longwell manufactured by the Defendants was not therapeutically equivalent to brand Diovan, was manufactured out of compliance with cGMPs, and was adulterated by its contamination with NDMA.

77. Defendants' generic Valsartan was sold illegally to Plaintiff Longwell.

K. Plaintiff James Childs's Individual Facts

78. Plaintiff James Childs is a New Jersey citizen.

79. Plaintiff Childs made numerous purchases of generic Valsartan manufactured by Defendants bearing various NDC numbers. Plaintiff Childs paid co-pays of at least $30 for Defendants' generic Valsartan.

80. The generic Valsartan purchased by Plaintiff Childs manufactured by the Defendants was not therapeutically equivalent to brand Diovan, was manufactured out of compliance with cGMPs, and was adulterated by its contamination with NDMA.

81. Defendants' generic Valsartan was sold illegally to Plaintiff Childs.

L. Extraterritorial Application of New Jersey or Massachusetts Law

82. As alleged above, Camber and Hetero USA named herein maintain their corporate headquarters in New Jersey.

83. The express and implied warranties alleged herein were made from and originated from Defendants' respective headquarters in New Jersey.

84. The mispresentations and/or material omissions regarding the therapeutic equivalence of the Defendants' Valsartan products to brand Diovan, and regarding the Defendants' cGMP violations and/or distribution of adulterated Valsartan in the United States were made from the Defendants' New Jersey.

85. Plaintiffs intend to seek additional discovery to show that Defendants' warranties and breach thereof, and violations of consumer protection statutes, and other breaches of common law occurred and emanated primarily from New Jersey, or otherwise as discovery shall demonstrate.

86. Alternatively, Plaintiffs intend to show that Defendants have sufficient contacts with Massachusetts to warrant application of Massachusetts law.

V. CLASS ACTION ALLEGATIONS

87. Plaintiffs bring this action both individually and as a class action pursuant to Fed. R. Civ. P. 23(a), 23(b)(2) and 23(b)(3) against Defendants on their own behalf and on behalf of the Nationwide Class defined below:

> All individuals in the United States of America and its territories and possessions who, since at least January 1, 2012, paid any amount of money out of pocket (for personal or household use) for Valsartan product manufactured by or for Defendants.

88. In the alternative, Plaintiffs allege sub-classes for all individuals in each State, territory, or possession who, since at least January 1, 2012, paid any amount of money out of pocket for Valsartan product manufactured by or for Defendants. Collectively, the foregoing Nationwide Class and alternative state sub-classes are referred to as the "Class."

89. Excluded from the Class are: (a) any Judge or Magistrate presiding over this action, and members of their families; (b) Defendants and affiliated entities, and their employees, officers, directors, and agents; (c) Defendants' legal representatives, assigns and successors; and (d) all

persons who properly execute and file a timely request for exclusion from any Court-approved class.

90. Plaintiffs reserve the right to narrow or expand the foregoing class definition, or to create subclasses as the Court deems necessary.

91. Plaintiffs meet the prerequisites of Rule 23(a) to bring this action on behalf of the Class.

92. Numerosity: While the exact number of Class Members cannot be determined without discovery, they are believed to consist of potentially millions of Valsartan consumers nationwide. The Class Members are therefore so numerous that joinder of all members is impracticable.

93. Commonality: Common questions of law and fact exist as to all Class Members, including but not limited to:

a. Whether each Defendant made express or implied warranties of "sameness" to Plaintiffs and Class Members regarding their generic Valsartan products;

b. Whether each Defendant's Valsartan product was in fact the same as brand Diovan consistent with such express or implied warranties;

c. Whether each Defendant's Valsartan product was contaminated with NDMA;

d. Whether each Defendant's Valsartan product containing NMDA was adulterated;

e. Whether Defendants violated cGMPs regarding the manufacture of their Valsartan products;

f. Whether each Defendant affirmatively misrepresented or omitted facts that its Valsartan product was the same as brand Diovan and thus therapeutically interchangeable;

g. Whether each Defendant affirmatively misrepresented or omitted facts regarding its compliance with cGMPs and/or was not adulterated;

h. Whether Plaintiffs and other Class Members have been injured as a result of each Defendant's unlawful conduct, and the amount of damages;

i. Whether a common damages model can calculate damages on a classwide basis;

j. When Plaintiffs' and Class Members' causes of action accrued;

k. Whether Defendants fraudulently concealed Plaintiffs' and Class Members' causes of action.

94. Typicality: Plaintiffs' claims are typical of Class Members' claims. Plaintiffs and Class Members all suffered the same type of economic harm. Plaintiffs have substantially the same interest in this matter as all other Class Members, and their claims arise out of the same set of facts and conduct as all other Class Members.

95. Adequacy of Representation: Plaintiffs are committed to pursuing this action and have retained competent counsel experienced in pharmaceutical litigation, consumer fraud litigation, class action, and federal court litigation. Accordingly, Plaintiffs and their counsel will fairly and adequately protect the interests of Class Members. Plaintiffs' claims are coincident with, and not antagonistic to, those of the other Class Members they seek to represent. Plaintiffs have no disabling conflicts with Class Members and will fairly and adequately represent the interests of Class Members.

96. The elements of Rule 23(b)(2) are met. Defendants have acted on grounds that apply generally to Class Members so that preliminary and/or final injunctive relief and corresponding declaratory relief is appropriate respecting the Class as a whole.

97. The elements of Rule 23(b)(3) are met. Here, the common questions of law and fact enumerated above predominate over the questions affecting only individual Class Members, and

a class action is the superior method for fair and efficient adjudication of the controversy. Although many other Class Members have claims against Defendants, the likelihood that individual Class Members will prosecute separate actions is remote due to the time and expense necessary to conduct such litigation. Serial adjudication in numerous venues is furthermore not efficient, timely or proper. Judicial resources will be unnecessarily depleted by resolution of individual claims. Joinder on an individual basis of thousands of claimants in one suit would be impractical or impossible. In addition, individualized rulings and judgments could result in inconsistent relief for similarly situated Plaintiffs. Plaintiffs' counsel, highly experienced in pharmaceutical litigation, consumer fraud litigation, class actions, and federal court litigation, foresee little difficulty in the management of this case as a class action.

FIRST CAUSE OF ACTION
BREACH OF EXPRESS WARRANTIES
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

98. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

99. Defendants expressly warranted that its Valsartan product was fit for its ordinary use, i.e., as an FDA-approved generic pharmaceutical that is therapeutically to and interchangeable with brand Diovan. In other words, Defendants expressly warranted that their products were the same as Diovan.

100. Defendants sold Valsartan product that they expressly warranted were compliant with cGMP and/or not adulterated.

101. Defendants' Valsartan product did not conform to each Defendant's express representations and warranties because the product was not manufactured in compliance with cGMP and/or was adulterated.

102. At all times relevant all fifty States and the District of Columbia and Puerto Rico

have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-313; Alaska Stat. § 45.02.313; Ariz. Rev. Stat. Ann. § 47-2313; Ark. Code. Ann. § 4-2-313; Cal. Com. Code § 2313; Colo. Rev. Stat. § 4-2-313; Conn. Gen. Stat. Ann. § 42a-2-313; 6 Del. Code. § 2-313; D.C. Code. § 28:2-313; Fla. Stat. Ann. § 672.313; Ga. Code. Ann. § 11-2-313; Haw. Rev. Stat. § 490:2-313; Idaho Code § 28-2-313; 810 Ill. Comp. Stat. Ann. 5/2-313; Ind. Code Ann. § 26-1-2-313; Kan. Stat. Ann. § 84-2-313; Ky. Rev. Stat. Ann. § 355.2-313; 11 Me. Rev. Stat. Ann. § 2-313; Md. Code. Ann. § 2-313; Mass. Gen. Law Ch. 106 § 2-313; Mich. Comp. Laws Ann. § 440.2313; Minn. Stat. Ann. § 336.2-313; Miss. Code Ann. § 75-2-313; Mo. Rev. Stat. § 400.2-313; Mont. Code Ann. § 30-2-313; Nev. Rev. Stat. U.C.C. § 104.2313; N.H. Rev. Ann. § 382-A:2-313; N.J. Stat. Ann. § 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.Y. U.C.C. Law § 2-313; N.C. Gen. Stat. Ann. § 25-2-313; N.D. Stat. § 41-02-313; Ohio Rev. Code Ann. § 1302.26; Okla. Stat. tit. 12A § 2-313; Or. Rev. Stat. § 72.3130; 13 Pa. C.S. § 2313; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-313; S.C. Code Ann. § 36-2-313; S.D. Stat. § 57A-2-313; Tenn. Code Ann. § 47-2-313; Tex. Bus. & Com. Code Ann. § 2-313; Utah Code Ann. § 70A-2-313; Va. Code § 8.2-313; Vt. Stat. Ann. 9A § 2-313; W. Va. Code § 46-2-313; Wash. Rev. Code § 62A 2-313; Wis. Stat. Ann. § 402.313 and Wyo. Stat. § 34.1-2-313.

103. At the time that Defendants marketed and sold its Valsartan product, they recognized the purposes for which the products would be used, and expressly warranted the products were the same as brand Diovan, and cGMP compliant and/or not adulterated. These affirmative representations became part of the basis of the bargain in every purchase by Plaintiffs and other Class Members.

104. Defendants breached its express warranties with respect to its Valsartan product as it was not of merchantable quality, was not fit for its ordinary purpose, and did not comply with

cGMP and/or was adulterated.

105. As a direct and proximate result of each Defendants' breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants' Valsartan product they purchased was so inherently flawed, unfit, or unmerchantable as to have essentially zero, significantly diminished, or no intrinsic market value.

SECOND CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

106. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

107. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2-314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Ann. Art. § 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382-A:2-314; N.J. Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2-314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31,

§ 3841, et seq.; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Utah Code Ann. § 70A-2-314; Va. Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. § 402.314 and Wyo. Stat. § 34.1-2-314.

108. Defendants were a merchant within the meaning of the above statutes.

109. Defendants' Valsartan product constituted "goods" or the equivalent within the meaning of the above statutes.

110. Defendants were obligated to provide Plaintiffs and other Class Members reasonably fit Valsartan product for the purpose for which the product was sold, and to conform to the standards of the trade in which Defendants are involved such that the product was of fit and merchantable quality.

111. Defendants knew or should have known that its Valsartan product was being manufactured and sold for the intended purpose of human consumption as a therapeutic equivalent to brand Diovan, and impliedly warranted that same was of merchantable quality and fit for that purpose.

112. Defendants breached its implied warranty because each Defendant's Valsartan product was not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

113. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants' Valsartan product they purchased was so inherently flawed, unfit, or unmerchantable as to have essentially zero, significantly diminished, or no intrinsic market value.

THIRD CAUSE OF ACTION
FRAUD
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

114. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

115. Defendants affirmatively misrepresented material facts including, inter alia, that their Valsartan products were therapeutically equivalent to brand Diovan and/or complied with cGMPs and/or were not adulterated.

116. Defendants failed to disclose material facts to render non-misleading its statements about, inter alia, that their Valsartan products were not therapeutically equivalent to brand Diovan and/or did not comply with cGMPs and/or were adulterated.

117. Defendants' actions had the effect of fraudulently inducing customers to pay in whole or in part for Defendants' Valsartan product – product which Defendants knew or should have known was not therapeutically equivalent to brand Diovan and/or did not comply with GMPs and/or were adulterated. Plaintiffs and other Class Members would not have paid some or all of the amounts they paid for Defendants' Valsartan product had they known the truth.

118. Defendants knew, or reasonably should have known, that their misrepresentations were materially false or misleading, or that the omission of material facts rendered such representations false or misleading.

119. Defendants also knew, or had reason to know, that their misrepresentations and omissions would induce Class members to pay for some or all of the cost of Defendants' Valsartan products.

120. Defendants' misrepresentations and omissions were material.

121. To the extent applicable, Defendants intended their misrepresentations and

omissions to induce Plaintiffs and other Class Members to pay for Defendants' Valsartan product.

122. But for these misrepresentations and omissions, Plaintiffs and other Class Members would have not have paid for Defendants' Valsartan product.

123. To the extent applicable, Plaintiffs and other Class Members were justified in relying on Defendants' misrepresentations and omissions. The same or substantively identical misrepresentations and omissions were communicated, to each Class member, including through product labeling and other statements by Defendants. No reasonable consumer would have paid what they did for Defendants' Valsartan product but-for Defendants' unlawful conduct. To the extent applicable, reliance may be presumed in these circumstances.

124. Plaintiffs and other Class Members were damaged by reason of Defendants' misrepresentations and omissions alleged herein.

FOURTH CAUSE OF ACTION AGAINST THE CAMBER DEFENDANTS VIOLATION OF MASSACHUSETTS CONSUMER FRAUD ACT (INDIVIDUALLY AND ON BEHALF OF THE CLASS)

125. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein. This claim is asserted on a nationwide basis against Defendants.

126. Plaintiffs and other members of the class are "persons" within the meaning of Mass. G.L. c. 93A, *et seq.*

127. Defendant's conduct alleged herein constitutes a "sale" within the meaning of Mass. G.L. c. 93A, *et seq*.

128. Plaintiff Longwell sent a written demand for relief to the Defendants pursuant to Mass. Mass. G.L. c. 93A § 9(3) prior to serving Defendants withthis lawsuit. The Defendants have not made a written tender of settlement.

129. The Massachusetts Consumer Fraud Protection Act ("MCFPA") declares unlawful

"[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Mass. G.L. c. 93A § 2(a).

130. Defendants have engaged in unfair and deceptive acts in trade and commerce which have the capacity and tendency to deceive and, in fact, did deceive Plaintiffs and the class, and damaged Plaintiffs and class members.

131. Defendants affirmatively misrepresented (and/or wrongfully concealed and omitted) that their Valsartan products were therapeutically equivalent to brand Diovan and/or were manufactured in compliance with cGMPs and/or were not adulterated. In fact, Defendants' Valsartan products were contaminated with NDMA resulting in Defendants' Valsartan products not being therapeutically equivalent to brand Diovan and not manufactured in compliance with cGMPs and in fact constituting adulterated pharmaceuticals.

132. Defendants committed unlawful, deceptive, and unconscionable trade practices by marketing, selling, and otherwise placing into the stream of commerce Defendants' Valsartan products on the premise they were therapeutically equivalent to brand Diovan and/or manufactured in compliance with cGMPs and/or were not adulterated.

133. Defendants wrongfully concealed, suppressed, and omitted to disclose that its Valsartan products were not therapeutically equivalent to brand Diovan and/or not manufactured in compliance with cGMPs and/or were in fact adulterated.

134. Defendant's misrepresentations and omissions had the capacity to mislead Plaintiffs and Class Members into believing (i) that Defendants' Valsartan Products were therapeutically equivalent to brand Diovan, (ii) were manufactured in accordance with cGMPs, and/or (iii) were not adulterated and were legal to sell in the United States when the opposite was true.

135. Had Defendants not made misrepresentations or not omitted such facts,

Defendants' Valsartan products would not have been available to Plaintiffs because, among other reasons, it would have been illegal for Defendants to even introduce their Valsartan products into the United States. Plaintiffs and the class members were injured as a result.

136. Because of Defendants' unlawful, deceptive, unfair, and unconscionable trade practices, Plaintiffs and other members of the class have suffered injury and damages – an ascertainable loss – in an amount to be determined at trial. Pursuant to the MCFPA, this court has the power to enjoin Defendants' conduct.

FIFTH CAUSE OF ACTION
VIOLATION OF STATE CONSUMER PROTECTION LAWS
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

137. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

138. Defendants have violated the consumer protection statutes as follows:

a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, *et seq.*;

b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq*.;

c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Arizona Rev. Stat. § 44-1522, *et seq*.;

d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq*.;

e. Defendants have violated the California Unfair Competition Law by engaging in unfair or deceptive acts or practices in violation of Cal. Bus. Prof. Code § 17200, *et seq.*;

f. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq*.;

g. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq*.;

h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq*.;

i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq*.;

j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq*.;

k. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. State 10-1-392, *et seq*.;

l. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq*.;

m. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq*.;

n. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation 815 ILCS 505/1, *et seq*.;

o. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq*.;

p. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code Ann. § 714H, *et seq*.;

q. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq*.;

r. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

s. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;

t. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*; Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

u. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

v. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

w. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

x. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*;

y. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.0 10, *et seq.*;

z. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;

aa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

bb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

cc. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

dd. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

ee. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

ff. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

gg. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

hh. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

ii. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*

jj. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

kk. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

ll. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

mm. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, *et seq.*;

nn. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

oo. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

pp. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

qq. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

rr. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-11-1, *et seq.*;

ss. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*;

tt. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;

uu. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*; Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

vv. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*;

ww. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*; and

xx. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 23 L.P.R.A. § 1001, *et seq.*, the applicable statute for the Commonwealth of Puerto Rico.

139. Defendants' conduct constitutes trade or commerce or other actionable activity

within the meaning of the above statutes.

140. Each Plaintiff and other Class Member are consumers or persons aggrieved by Defendants' misconduct within the meaning of the above statutes.

141. To the extent applicable, each Defendants knew, intended, or should have known that their fraudulent and deceptive acts, omissions, or concealment would induce reliance and that reliance can be presumed under the circumstances.

142. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiffs and other Class Members have suffered damages in an amount – an ascertainable loss – to be proved at trial.

SIXTH CAUSE OF ACTION
UNJUST ENRICHMENT
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

143. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

144. As alleged herein, Defendants were unjustly enriched at the expense of Plaintiffs and other Class Members by virtue of the latter's paying for Defendants' Valsartan product.

145. Defendants profited immensely from introducing a carcinogen into the United States for human consumption. On top of that, because Defendants' Valsartan products were adulterated, their distribution and sale in the United States was illegal.

146. Plaintiffs and other Class Members were unjustly deprived of money obtained by Defendants as a result of the improper amounts paid for Defendants' Valsartan product. It would be inequitable and unconscionable for Defendants to retain the profit, benefit, and other compensation obtained from Plaintiffs and other Class Members as a result of their wrongful conduct alleged in this Complaint.

147. Plaintiffs and other Class Members are entitled to seek and do seek restitution from

Defendants as well as an order from this Court requiring disgorgement of all profits, benefits, and other compensation obtained by Defendants by virtue of its wrongful conduct.

SEVENTH CAUSE OF ACTION
NEGLIGENCE
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

148. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

149. Defendants owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacturing of its Valsartan product.

150. Defendants owed a duty to Plaintiffs and the Class to ensure that the Valsartan product it sold in the United States was therapeutically equivalent to brand Diovan and/or complied with cGMPs and/or was not adulterated.

151. Defendants owed a duty to care to Plaintiffs and the Class because they were the foreseeable, reasonable, and probable user of Valsartan product and victim of each Defendant's fraudulent and deceptive activities. Defendants knew, or should have known, that its Valsartan product was not therapeutically equivalent to brand Diovan and/or did not comply with cGMPs and/or were adulterated, and each was in the best position to uncover and remedy these shortcomings.

152. Defendants failed to do this. Defendants inadequately oversaw the manufacture and sale of its own Valsartan product. Defendants knew that ignoring the manufacturing issues surrounding its Valsartan product would damage Plaintiffs and the Class and increase its own profits.

153. Defendants maintained or should have maintained a special relationship with Plaintiffs and the Class, as they were obligated to ensure that its Valsartan product complied with cGMPs and/or was not adulterated.

154. Defendants' own actions and inactions created a foreseeable risk of harm to Plaintiffs and the Class. Each Defendant's misconduct included, but was not limited to, failing to oversee actions taken in the manufacture and sale of its Valsartan product.

155. Defendants breached the duties owed to Plaintiffs and the Class by failing to exercise reasonable care sufficient to protect the interests and meet the needs of Plaintiffs and the Class.

156. As a direct and proximate result of each Defendants' negligent conduct, Plaintiffs and the Class has suffered injury and are entitled to damages in an amount to be proven at trial.

EIGTH CAUSE OF ACTION
NEGLIGENCE PER SE
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

157. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

158. Defendants owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacturing of its Valsartan product.

159. Defendants owed a duty to Plaintiffs and the Class to ensure that the Valsartan product it sold in the United States was therapeutically equivalent to brand Diovan and/or complied with cGMPs and/or was not adulterated.

160. Defendants owed a duty to Plaintiffs and the Class because each State, territory, and possession has adopted and/or adheres to federal cGMP and adulteration standards.

161. Defendants failed to comply with federal cGMPs and/or federal adulteration standards.

162. As a result of Defendants' failures to do so, each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiffs and the Class.

163. As a direct and proximate result of each Defendants' negligent conduct, Plaintiffs and the Class has suffered injury and are entitled to damages in an amount to be proven at trial.

JURY DEMAND

Plaintiffs respectfully request a trial by jury on all causes of action so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for the following judgment:

A. An Order certifying this Action as a class action;

B. An Order appointing Plaintiffs as Class Representative, and appointing undersigned counsel as Class Counsel to represent the Class;

C. A Declaration that Defendants are liable pursuant to each and every one of the above-enumerated causes of action;

D. An Order awarding appropriate preliminary and/or final injunctive relief against the conduct of Defendants described herein;

E. Payment to Plaintiffs and Class Members of all damages, exemplary or punitive damages, and/or restitution associated with the conduct for all causes of action in an amount to be proven at trial;

F. An award of attorneys' fees, expert witness fees, and costs, as provided by applicable law and/or as would be reasonable from any recovery of monies recovered for or benefits bestowed on the Class Members;

G. An award of statutory penalties to the extent available;

H. Interest as provided by law, including but not limited to pre-judgment and post-judgment interest as provided by rule or statute; and

I. Such other and further relief as this Court may deem just, equitable, or proper.

Dated: December xx, 2020

RESPECTFULLY SUBMITTED,

/s/ *David J. Stanoch*

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